

SHOTWELL & CARR, INC.

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December 29, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm. 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 99N-1415
Supplements and other Changes to
Approved New Animal Drug Application

To Whom it May Concern:

On behalf of the Animal Drug Alliance please accept the following comments in regard to Docket No. 99N-1415.

The Animal Drug Alliance has reviewed the above proposed regulation along with the draft guidance document entitled, "Guidance for Industry: Chemistry, Manufacturing and Control Changes to an Approved NADA or ANADA" (Guidance Document #83).

October 1, 1999 to December 15, 1999 is an extremely short time for review of such a major proposed change and we request an extension of that response deadline date. In addition to this request, we hereby request an open meeting with the Center for Veterinary Medicine for direct interaction on the guidance document. There are a number of issues in this document which are completely ambiguous and warrant discussions before this draft is finalized. Brief examples of some of these issues are as follows:

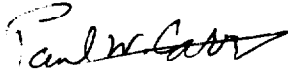
1. There are several statements such as, "...not otherwise listed as a major change." Or "...except as otherwise listed." We believe many of these so noted issues are not well defined.
2. Comparability Protocols – Since this is mentioned in the proposed regulations and guidance document, industry must know what this entails, what the time frames for review are, etc.
3. Page 10 of the draft guidance document, item B.6. is not at all clear. It seems the word "modified" perhaps should be "immediate."
4. It was noted that a minor change is allowed to add an ink or code imprint to solid oral dosage form drug products if the ink was previously used on CVM or CDER approved products. It is difficult to understand how a firm is to determine what inks have been previously used on CVM or CDER approved products.

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We look forward to the opportunity for open discussions of these and other issues..

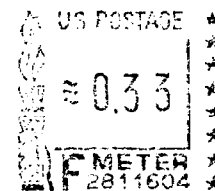
Sincerely,

A handwritten signature in black ink, appearing to read "Paul W. Carr". The signature is fluid and cursive, with a prominent loop at the end.

Paul W. Carr, Chairman
Animal Drug Alliance

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